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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,005	06/06/2000	CHRISTOPH VON EICHEL-STREIBER	113.1007	2246

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EXAMINER	
PARAS JR, PETER	
ART UNIT	PAPER NUMBER
1632	19

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/581,005	Applicant(s) VON EICHEL-STREIBER ET AL.	
	Examiner Peter Paras, Jr.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-51* is/are pending in the application.

4a) Of the above claim(s) *35-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment received on 7/8/02 has been entered. Claim 31 has been amended. Claims 23-51 are pending. Claims 23-34 are under current consideration.

Election/Restrictions

Claims 35-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 12/11/97. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of claims 23-34 under 35 U.S.C. 112, first paragraph has been withdrawn.

The following are new grounds of rejection under 35 USC § 112, 1st paragraph:

Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to bacteria, particularly *Listeria*, that comprise a gene that shares 35% identity with dapE or cspL.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

The DNA sequences that encode all genes that share 35% identity with the disclosed dapE and cspL genes as set forth in SEQ ID NOs 1 and 2 encompassed within the genus of dapE and cspL genes have not been disclosed. Based upon the prior art there is expected to be sequence variation among the species of cDNA, which encode dapE and cspL. The specification has taught the nucleotide sequences of a

dapE and cspL gene as set forth in SEQ ID NOs 1 and 2, respectively. The specification however has not disclosed the sequences of any of the DNA molecules, which share 35% identity with SEQ ID NOs 1 and 2. There is no evidence on the record of a relationship between the structures of the DNA molecules encoding any dapE or cspL that would provide any reliable information about the structure of DNA molecules within the genus. There is no evidence on the record that any of the nucleotide sequences embraced by the claims had known structural relationships to each other; the art indicated that there is variation between DNA sequences encoding dapE and cspL. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

In the instant case the claimed embodiments of DNA molecules that share 35% identity with the dapE and cspL genes as set forth in the nucleotide sequences of SEQ ID NOs 1 and 2 encompassed within the genus of dapE and cspL genes lack a written description. The specification fails to describe what DNA molecules fall into this genus and it was unknown as of Applicant's effective filing date that any of these DNA molecules would have the property of encoding functional dapE or cspL. The skilled

artisan cannot envision the detailed chemical structure of the encompassed DNA molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus of DNA molecules encoding dapE or cspL. Moreover, the art has recognized that there would be variation among the species of the genus of DNA molecules that encode dapE or cspL. Therefore, Applicant has provided only a description for the dapE and cspL genes as set forth in SEQ ID NOs 1 and 2. However, Applicant was not in possession of the genus of DNA molecules that encode dapE or cspL as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

The following are new grounds of rejection under 35 USC § 112, 2nd paragraph:

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite as written. The claim as written recites that expression of a foreign DNA as being under the control of a eukaryotic regulator gene. Neither the specification nor the prior art of record have provided a definition of a eukaryotic regulator gene that can control expression of a DNA sequence. It would appear that Applicants intended to recite that expression of a foreign DNA sequence is controlled by a eukaryotic regulatory sequence such as a promoter. Correction is required. Claims 24-34 depend from claim 23.

The following are new grounds of rejection under 35 USC § 102:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-24, 26, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Goossens et al (International Immunology, 1995, 7(5): 797-805).

Goossens et al teach an attenuated strain of *Listeria monocytogenes*, actA-, which is viable in a host organism but is restricted in its intracellular motility. The actA- strain is able to reach its target tissue by its normal route of infection but is attenuated in virulence. See page 803, column 2, the last paragraph. Goossens et al teach insertion of a nucleotide sequence encoding the nucleoprotein (NP) of the lymphocytic choriomeningitis virus (LCMV), wherein the NP coding sequence is under control of the hly promoter into a plasmid, which is subsequently introduced into the actA- strain. See page 798, in the section entitled "Methods" and also see page 800. *Listeria* can infect cow udders as evidenced by Bryner et al [(Acta Microbiologica Hungarica, 1989, 36(2-3): 137-140); see page 137].

Thus, the teachings of Goossens anticipate all of the instant claim limitations.

Claims 23-24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Branstrom et al (WO 97/08955).

Branstrom et al teach an attenuated strain of *Shigella flexneri* that can enter a host cell by its normal route of infection and infect mucosal epithelial cells of the gut, but is unable to grow in the absence of diaminopimelate (DAP). See page 5. Branstrom et al further teach that such a strain may be useful for transferring genes such as the CFTR gene for the purpose of gene therapy. See page 14, wherein a plasmid comprising a nucleic acid sequence of interest can be introduced into the *Shigella* strain. See pages 21-23 and throughout the entire document. Branstrom et al teach that the CMV promoter can be used to direct expression of a heterologous gene of interest.

Thus, the teachings of Branstrom anticipate all of the instant claim limitations.

Claims 23-24, 26, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Dietrich et al (Nature Biotechnology, 1998, 16: 181-185).

Dietrich et al teach an attenuated strain of *Listeria monocytogenes*, Δ2, which is viable in a host organism but is restricted in its intracellular motility. The Δ2 strain is able to reach its target tissue by its normal route of infection but is attenuated in virulence. See page 181. Dietrich et al teach insertion of a nucleotide sequence encoding the green fluorescent protein (GFP), wherein the GFP coding sequence is under control of the actA promoter into a plasmid, which is subsequently introduced into the Δ2 strain. See page 182. *Listeria* can infect cow udders as evidenced by Bryner et

al [(Acta Microbiologica Hungarica, 1989, 36(2-3): 137-140); see page 137]. Finally, Dietrich et al teach the insertion of an exogenous suicide gene, ply118, such that expression of ply118 results in lysis of the Δ2 strain. See page 182.

Thus, the teachings of Dietrich et al anticipate all of the instant claim limitations.

Conclusion

No claim is allowed. Claims 27-34 appear to be free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS
PATENT EXAMINER